

WHAT IS CLAIMED IS:

*Sub A1*

1. A vaccine formulation for oral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles sized such that at least 50% of the microparticles are less than 5  $\mu\text{m}$ , the microparticles comprising at least one antigen entrapped or encapsulated by a biodegradable polymer.

*a*

2. The ~~vaccine formulation~~ *method* of Claim 1, wherein the microparticles are sized such that at least 50% of the microparticles are less than 3  $\mu\text{m}$ .

*Sub A2*

3. The vaccine formulation of Claim 1, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid or enantiomers thereof.

4. The vaccine formulation of Claim 1, wherein the microparticles are formed using a solvent evaporation ~~method~~.

*a*

5. The ~~vaccine formulation~~ *method* of Claim 1, wherein the antigen comprises a *B. pertussis* antigen.

*a*

6. The ~~vaccine formulation~~ *method* of Claim 1, wherein the microparticles comprise at least 2 subpopulations of microparticles, each subpopulation comprising a different antigen entrapped or encapsulated by a biodegradable polymer.

*Sub A3*

7. A vaccine formulation for oral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of nanoparticles sized such that at least 50% of the nanoparticles are less than 600nm, the nanoparticles comprising at least one antigen entrapped or encapsulated by a biodegradable polymer.

*c*  
*SVB*  
*D1*

8. The ~~vaccine formulation~~ *method* of Claim 7, wherein the nanoparticles are sized such that at least 50% of the microparticles are less than 500nm.

Sub 4  
9. The vaccine formulation of Claim 7, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid or enantiomers thereof.

10. The vaccine formulation of Claim 7, wherein the nanoparticles are formed using a coacervation method.

a  
11. The vaccine formulation of Claim 7, wherein the antigen comprises a *B. pertussis* antigen.

Sub 5  
12. The vaccine formulation of Claim 7, wherein the nanoparticles comprise at least 2 subpopulations of nanoparticles, each subpopulation comprising a different antigen entrapped or encapsulated by a biodegradable polymer.

Sub 5  
13. A method of inducing a protective immune response against *B. pertussis*, comprising orally administering to a subject a pharmaceutically effective amount of microparticles sized such that at least 50% of the microparticles are less than 5  $\mu$ m, the microparticles comprising at least one *B. pertussis* antigen entrapped or encapsulated by a biodegradable polymer.

14. The method of Claim 13, where the microparticles are sized such that at least 50% of the microparticles are less than 3  $\mu$ m.

Sub 6  
15. The method of Claim 13, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid and enantiomers thereof and wherein the microparticles are formed using a solvent evaporation method.

16. The method of Claim 13, wherein the at least one *B. pertussis* antigen is selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA), pertactin and fimbriae and combinations thereof.

17. A method of inducing a protective immune response against *B. pertussis*, comprising orally administering to a subject a pharmaceutically effective amount of nanoparticles sized such that at least 50% of the nanoparticles are less than

~~The method of Claim 17, wherein the microparticles are less than 500 nm.~~

- Sub A 7

20. The method of Claim 17, wherein the at least one *B. pertussis* antigen is selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA), pertactin and fimbriae and combinations thereof.

add B5

add  $D'$